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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,445	01/09/2004	Robert A. Ganz	021827-000140US	7989

7590 09/05/2006

CHRISTIANA STATE (REG. NO. 52,045)
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EXAMINER	
VRETTAKOS, PETER J	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/754,445	GANZ ET AL.	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *see attached*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

6-19-06; 6-8-05; 2-3-05; 4-26-04

DETAILED ACTION

Claims 28-49 are pending. Claim 28 is independent. The Applicant has filed an amendment dated 6-19-06.

This application is from a family of applications and/or patents involving esophageal tissue treatment some of which are:

1) 10/426,923 Ex. Vrettakos AU3739

2) 10/370,645 Ex. Vrettakos AU3739 At Appeal as of 8-29-06.

3) 10/754,444 Ex. Toy AU3739

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28-33 and 37-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards (6,405,732).

Edwards et al. (6,405,732) discloses:

28. A system (10) *for treating mucosal tissue* ***(col. 12:34-40)*** in an esophagus (6), said system comprising: an elongated member (18); an energy delivery structure (20) deployable (it is a "balloon, frame or cage" – language from Applicant's specification) from the elongated member (18) and adapted to deliver energy (col.

11:27-50; treatment electrodes 22, col. 7:48-53; 88) to at least a portion of a circumferential section (see patented claim 11) *of the mucosal lining* ***(col. 12:34-40)*** of the esophagus (6); and means for delivering energy (22, 88) through the delivery structure under conditions (Edwards system permits changes to duration of power and total energy selected, col. 12:41-46) selected *to initiate regrowth* (this is inherent through an ablative protocol, of which Edwards' system is capable, involving conditions created by manipulating the duration of power and total energy selected) of a mucosal layer *without substantial injury to a submucosal layer* (preservation of the submucosal layer is suggested in patented claim 20) underlying the mucosal layer. (Also note feedback control is disclosed in patented claim 26.)

29. A system as in claim 28, wherein the energy delivery structure comprises an expandable structure (20, figure 11a) deployable from the elongated member.

30. A system as in claim 29, wherein the expandable structure comprises an expandable balloon (55, figure 5b).

31. A system as in claim 30, wherein the balloon is non-distensible and dimensionally stable (as a result of element arms 44).

32. A system as in claim 30, wherein the balloon is elastic (inherent).

33. A system as in any of claims 30 to 32, wherein the energy delivery structure further comprises an electrode (22, treatment and/or mapping electrodes, col. 7:50-53) array.

37. A system as in claim 33, wherein the balloon includes electrodes of a common polarity (col. 11:65-67) formed over at least a portion of its exterior surface.

38. A system as in claim 33, wherein the balloon includes electrodes of a common polarity formed over at least a portion of its inner (figure 11a) surface.

39. A system as in any of claims 30 to 32, wherein the balloon is inflatable with a conductive medium to form a monopolar electrode.

40. A system as in claim 29, wherein the expandable structure comprises a frame (50, figure 4b) deployable from the elongated member (18) and an electrode array (22) formed over at least a portion of the frame.

41. A system as in claim 40, wherein the frame comprises an arcuate surface (clearly depicted in figure 4b) which carries the electrodes (22) to engage a partial section of the circumference of the esophagus.

42. A system as in claim 41, wherein the frame comprises two oppositely facing arcuate surfaces. Again, clearly depicted in figure 4b.

43. A system as in claim 28, wherein the energy delivery structure comprises a heating structure. See col. 11:27-50.

44. A system as in claim 43, wherein the heating structure comprises a radiation heat source. See col. 11:27-50, especially line 40.

45. A system as in claim 44, wherein the energy delivery structure further comprises a pair of expandable centering elements (20 in figure 3) disposed distally and proximally of the radiation heat source (22,88; col. 11:27-50, especially line 40).

46. A system as in any one of claims 43 to 45, wherein the radiation heat source is a filament, spherical radiator, cylindrical radiator, or polygonal radiator. In figures 3 and 4b element 22 (heat source) is a cylindrical.

47. A system as in claim 28 wherein the energy delivery means comprises a photonic source. See col. 11:27-50.

48. A system as in claim 28, wherein the energy delivery means comprises a radiofrequency power supply. See col. 11:27-50.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-36 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (6,405,732).

Edwards is silent regarding *specific* electrode spacing dimensions, however, the patent discloses alternate electrode spacing and its relation to the spacing's effect on lesion creation (col. 14:33-47; also see patented claim 11 toward the desirability of different lesion patterns) thereby making electrode spacing "no more than 3mm" obvious and easily determined through routine experimentation. The motivation to perform the experiments would be to understand the effects of the size of the spacings on lesion creation.

34. A system as in claim 33, wherein the electrode array comprises bipolar electrode pairs (col. 11:65 through col. 12:11; elements 88 are equated to elements 22) formed over at least a portion of the outer surface of the balloon (see figure 11a), wherein the spacing between the electrodes is no more than 3 mm.

35. A system as in claim 34, wherein the electrodes are aligned axially on the balloon. See figure 18b.

36. A system as in claim 34, wherein the electrodes are aligned circumferentially over the balloon. See figures 18a,c.

49. A system as in claim 48, wherein the radiofrequency power supply is adaptable to deliver an energy dosage in the range from 1 J/cm.sup.2 to 50 J/cm.sup.2 over a time period less than 5 seconds. The parameters would be obvious in light of routine experimentation. Furthermore, Edwards system permits changes to duration of power and total energy selected (col. 12:41-46).

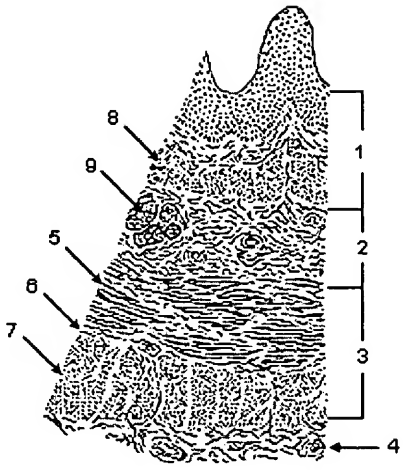
Further, the parameters are intended use. A recitation of the intended use of the claimed invention must result in a *structural difference* between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The Office contends that at least one of the Edwards' embodiments is structurally capable of the claimed parameters.

Response to Arguments

The prior 35 USC § 112 rejection is obviated through the amendment to claim 33.

Applicant's arguments filed 6-19-06 have been fully considered but they are not persuasive.

For future reference:



1. Mucosa
2. Submucosa
3. Muscularis
4. Adventitia
5. Striated muscle
6. Striated and smooth
7. Smooth muscle
8. Lamina muscularis mucosae
9. Esophageal glands

The image is from:

http://training.seer.cancer.gov/ss_module07_ugi/unit02_sec04_anatomy.html.

It is important to note in the following analysis that the standard for anticipation (for system claims) is to determine that the prior art is *capable* of delivering energy to initiate regrowth of mucosal tissue without substantial injury to an underlying submucosal layer, and not necessarily *express* disclosure targeting mucosal tissue that initiates regrowth without substantial injury to the submucosal layer.

Edwards discloses creating a lesion at a mucosal surface (col. 12:34-41; surface is certainly equivalent to "shallow depth"; Edwards discloses 1 to 5mm beneath the mucosal surface) in an esophagus (col. 12:39) capable of "preserving"/avoiding substantial injury to a submucosal layer (see patented claim 20). Edwards also discloses that several parameters can be controlled during energy delivery (col. 12:41-

46) including **RF power delivered to the electrode, duration of power delivery and total energy delivered** (e.g. joules) all while minimizing heating and injury to nearby tissue (as would be the case in targeting mucosal tissue while avoiding submucosal tissue; see patented claim 20 and col. 12:46-51).

The Applicant argues that the present application "means" delivers energy to mucosal tissue at "relatively" (vague) high levels of **power** for "relatively" (vague) short periods of **time** in order to achieve the shallow depth of treatment desired. In response, the Office has pointed out above that Edwards discloses targeting a shallow depth ("mucosal *surface*"; col. 12:34-41; surface is certainly equivalent to "shallow depth"; Edwards also discloses 1 to 5mm beneath the mucosal surface) with control of **power** and **time** of energy application strongly inferring that Edwards is *capable* of delivering energy to initiate regrowth of mucosal tissue without substantial injury to an underlying submucosal layer (again, see patented claim 20 where selective preservation is disclosed), thereby anticipating Applicant's independent claim 28. Also see more disclosure regarding control of **power** and **time** through microprocessor 394 in col. 19:28-33. Nothing in the Edwards patent precludes the disclosed embodiments from delivering energy at "relatively high levels of **power** for relatively short periods of **time**".

The Applicant argues that the present application "means" in the last limitation of application claim 28 is taught as modified electrode patterns such as those shown in application figures 7a-d. In response, the Office asserts that Edwards discloses several times (see col. 16:5-8) control of the pattern of energy delivered thereby making inherent different electrode patterns including those in figures 18a-d (analogous to

actual electrode patterns depicted in the Applicant's figures 7a-d). Also see col. 14:33-47 for disclosure of various electrode patterns.

Moreover, MPEP § 2112.1 states, "something which is old does not become patentable upon a new discovery". Applied to the instant application, the Office asserts that Edwards' silence towards "initiat[ing] regrowth of a mucosal layer" is patentably irrelevant in light of the MPEP section. The Office has posited Edwards, which discloses targeting the mucosal layer in the esophagus (sphincter) with energy along with the capability of changing the amount of **power** and **time** the energy is applied. This disclosure makes inherent a means for delivering energy through the delivery structure under conditions selected (**power** and **time** related according to the Applicant) **to initiate regrowth of a mucosal layer** without substantial injury to a submucosal layer underlying the mucosal layer.

Edwards does not *expressly* disclose energy dosage ranges. However, the patent is replete with examples of structure capable of delivering energy at different times and powers as mentioned above, therefore Edwards inherently discloses the capability of delivering energy at the relatively short time and relatively high power the Applicant argues and claims (through energy dosage ranges).

Double Patenting

Application 2004/0215235 includes claim 56, which lists the same energy dosage ranges as the instant application's claim 49. Claim 57 lists a time application below 5 seconds just as the instant application's claim 49. The Applicant has argued in the instant application that their "means" in claim 28 delivers energy at a relatively short

time and relatively high power thereby permitting initiation of regrowth. The Applicant actually claims this combination of time and power in claim 49. Therefore, because the combination of time and power required to "initiate regrowth of a mucosal layer" according to the Applicant is actually claimed in 2004/0215235, it is inherent that the device in 2004/0215235 includes a "means" for initiating regrowth. The rejection is maintained.

Application 2004/0087936 includes paragraph 96, which lists overlapping energy dosage ranges as the instant application's claim 49. Paragraphs 98 ("between 5 and 20 seconds") and 100 ("to obtain shallower lesions than the ones obtained in the above-mentioned study the RF energy applied may be increased while decreasing the treatment time" just mentioned as "between 5 and 20 seconds") imply a time application below 5 seconds just as the instant application's claim 49. The Applicant has argued in the instant application that their "means" in claim 28 delivers energy at a relatively short time and relatively high power thereby permitting initiation of regrowth. The Applicant actually claims this combination of time and power in claim 49. Therefore, because the combination of time and power required to "initiate regrowth of a mucosal layer" according to the Applicant is actually disclosed in 2004/0087936, it is inherent that the device in 2004/0087936 includes a "means" for initiating regrowth. The rejection is maintained.

Application 2005/0171524 includes paragraph 75, which lists overlapping energy dosage ranges as the instant application's claim 49. Paragraph 76 lists a time application below 5 seconds just as the instant application's claim 49. The Applicant

has argued in the instant application that their "means" in claim 28 delivers energy at a relatively short time and relatively high power thereby permitting initiation of regrowth. The Applicant actually claims this combination of time and power in claim 49. Therefore, because the combination of time and power required to "initiate regrowth of a mucosal layer" according to the Applicant is actually disclosed in 2005/0171524, it is inherent that the device in 2005/0171524 includes a "means" for initiating regrowth. The rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-89 of

copending Application No. 2004/0215235. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim expandable energy delivery catheters used in the esophagus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 28-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-96 of copending Application No. 2004/0087936. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim expandable energy delivery catheters used in the esophagus.
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Claims 28-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 2005/0171524. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim expandable energy delivery catheters used in the esophagus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The Applicant should file terminal disclaimers in the other Applications, as well.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
August 27, 2006

MICHAEL PEFFLEY
PRIMARY EXAMINER